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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/386,266	08/31/1999	DAVID J. BRAYDEN	99.1080.US	1219

7590 07/28/2005

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/386,266

Applicant(s)

BRAYDEN, DAVID J.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 35-47 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-47 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date: _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____  | 6) <input type="checkbox"/> Other: _____                                    |

## **REQUEST FOR CONTINUED EXAMINATION**

1) A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicants' submission filed on 04/21/05 has been entered.

### **Applicants' Amendment**

2) Acknowledgment is made of Applicants' amendment filed 04/21/05 in response to the final Office Action mailed 10/18/04.

### **Status of Claims**

3) Claims 35, 39, 41 and 45 have been amended via the amendment filed 04/21/05.  
New claim 47 has been added via the amendment filed 04/21/05.  
Claims 35-47 are pending and are under examination.

### **Prior Citation of Title 35 Sections**

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

### **Prior Citation of References**

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Rejection(s) Withdrawn**

6) The rejection of claims 35 and 41 made in paragraph 11 of the Office Action mailed 10/18/04 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to the claim.

7) The rejection of claim 35 made in paragraph 12(a) of the Office Action mailed 10/18/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

- 8) The rejection of claim 41 made in paragraph 12(b) of the Office Action mailed 10/18/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 9) The rejection of claim 37 made in paragraph 12(c) of the Office Action mailed 10/18/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.
- 10) The rejection of claim 43 made in paragraph 12(d) of the Office Action mailed 10/18/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.
- 11) The rejection of claim 45 made in paragraph 12(e) of the Office Action mailed 10/18/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 12) The rejection of claim 41 made in paragraph 12(f) of the Office Action mailed 10/18/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 13) The rejection of claim 45 made in paragraph 12(g) of the Office Action mailed 10/18/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.
- 14) The rejection of claim 46 made in paragraph 12(h) of the Office Action mailed 10/18/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.
- 15) The rejection of claims 36-40 and 41-46 made in paragraph 12(h) of the Office Action mailed 10/18/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

**Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)**

- 16) Claims 46 and 47 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of

the claimed invention. This is a new matter rejection.

New claim 47 claims a vaccine formulation comprising at least two subpopulations of microparticles each comprising a different antigen entrapped or encapsulated by a biodegradable polymer 'wherein said microparticles are sized such that the average diameter of said microparticles is from about 2.2  $\mu\text{m}$  to about 4.3  $\mu\text{m}$ '. Claim 46, as amended, also includes similar limitations. Applicants state that support for the new claim 47 is found in the originally filed claim 20. However, the originally filed claim 20 does not support the claimed vaccine formulation as recited comprising at least two subpopulations of microparticles each comprising a different antigen entrapped or encapsulated by a biodegradable polymer 'wherein said microparticles are sized such that the average diameter of said microparticles is from about 2.2  $\mu\text{m}$  to about 4.3  $\mu\text{m}$ '. The original claim 20 does not recite 'microparticles are sized such that the average diameter of said microparticles is from about 2.2  $\mu\text{m}$  to about 4.3  $\mu\text{m}$ '. Therefore, the new limitations in the instant claim are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P. 608.04 to 608.04(c).

Applicants are invited to point to specific line and page numbers in the specification, as originally filed, that provide descriptive support for the limitations identified above, or to remove the new matter from the claims.

**17)** Claims 35, 41, 46, 47 and those dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The recitation of broader scope in claims 35 and 41: 'wherein said microparticles are sized ...' is new matter. The limitation: microparticles is from 'about' 2.2  $\mu\text{m}$  to 'about' 4.3  $\mu\text{m}$  in claims 35, 41, 46 and 47 is new matter. In the amendment filed 10/08/03, Applicants stated that support for claims 35 to 46 can be found throughout the application, particularly on page 5, lines 13 to 21, page 15, lines 5 to 9, page 16, lines 19 to 20, Table 1 on page 16, Table 2 on page 17, and in originally filed claims 1 to 5 and 15 to 20. However, the description in these parts of the

specification and the original claims is limited to a vaccine formulation and a method of inducing  $T_H1$  polarized immune response comprising parenteral administration to a subject microparticles comprising an antigen entrapped or encapsulated in a biodegradable polymer where 'at least 50% of said microparticles' are sized as recited in the instant claims. The above identified limitation in the claims are of much broader scope and encompass less than 50% percentage of microparticles having the recited size for which there is no descriptive support in the instant specification, including original claims 1-5 and 15-20. Furthermore, there is no descriptive support in the instant specification, as originally filed, for microparticles is from 'about' 2.2  $\mu m$  to 'about' 4.3  $\mu m$ . Therefore, the new limitations in the instant claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P. 608.04 to 608.04(c).

Applicants are invited to point to specific line and page numbers in the specification, as originally filed, that provide descriptive support for the limitations identified above, or to remove the new matter from the claims.

### **Rejection(s) under 35 U.S.C. § 112, Second Paragraph**

**18)** Claims 35-47 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 35, 41, 46 and 47 are vague and indefinite in the limitation: 'about' 2.2  $\mu m$  to 'about' 4.3  $\mu m$ , because it is unclear what is encompassed in the term 'about' is not clear. Does the limitation 'about' encompass  $\pm 10$  or  $\pm 5$ ?

(b) Claim 42 is incorrect and confusing in the limitation: less than 3 m' (see line 2), because it is unclear what does 'm' stand for. Is this a unitage for the size of microparticles?

(c) Claim 46 is vague, indefinite, confusing and/or lack proper antecedent basis in the limitation: 'a different antigen' entrapped or encapsulated by 'a biodegradable polymer'. Claim 46 depends from claim 41, which already recites 'a biodegradable polymer' and 'at least one antigen'. Is 'a ... antigen' or 'a biodegradable polymer' recited in the dependent claim 46 different from the one recited in the base claim? The dependent claim 46 appears to be internally inconsistent in

scope.

(d) Claims 35, 41 and 47 are vague and indefinite in the limitation: inducing or enhancing 'a  $T_H1$  polarized immune response', because it is unclear to what element is the  $T_H1$  polarized immune response directed to: at least one antigen, biodegradable polymer, or microparticles?

(e) Claims 36-40 and 42-46, which depend directly or indirectly from claim 35 or 41, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

### **Objection(s)**

**19)** Claims 46 and 47 are objected to for being substantial duplicates of each other. Applicants are advised that should claim 46 be found allowable, claim 47 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### **Remarks**

**20)** Claims 35-47 stand rejected.

**21)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The central Fax number for submission of amendments, responses and papers is (571) 273-8300.

**22)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**23)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. The Examiner


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can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

July, 2005

  
S. DEVI, PH.D.  
PRIMARY EXAMINER